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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,015	02/12/2001	Edmund Y.M. Chein	00115P002D	2156
8791	7590	05/27/2004	EXAMINER	
BLAKELY SOKOLOFF TAYLOR & ZAFMAN 12400 WILSHIRE BOULEVARD, SEVENTH FLOOR LOS ANGELES, CA 90025			GUPTA, ANISH	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,015

Applicant(s)

CHEIN, EDMUND Y.M.

Examiner

Anish Gupta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed, 4-22-04 is acknowledged. Claims 10 and 14 were amended. Claims 10-20 are pending in this application.
2. All rejection made in the previous office action are hereby withdrawn and new grounds of rejections follow below.
3. The indicated allowability of claim 18 is withdrawn in view of the newly discovered reference(s) to Chein (GB 2320190). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chein (GB2320190).

The claims are drawn to kit with human growth hormone and a supplemental hormone that is administered separately.

The reference teaches hormone replenishment kit comprising growth hormone and at least two of supplemental hormone selected from the group consisting of sex hormone, melatonin hormone, adrenal hormone, thyroid hormone, and thymus hormone (see claim 21). The reference discloses that the regimen is for the replenishment of HGH and the two supplement hormone to a

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predetermined physiological level (see claim 21). The reference discloses, similar to the instant application claim 11, that the human growth hormone dosage is provided intravenously in a dose of less than .5mg per day (see claim 22). Further, the reference states that sex hormones is testosterone, progesterone and the adrenal hormone comprises dehydroepiandrosterone and pregnenolone (see claims 29 and 30). The reference discloses that pregnenolone is used in a the concentration of 100-200 µg/mL to attain the target blood level in a capsule form (see page 29, lines 13-20). Specifically, the reference discloses the administration to patients IGF-I (HGH), and supplemental hormones such as testosterone and pregnenolone, in a concentration of 50 per/day, 200 mg/day, and 100 mg/day (see page 31-34). Note that the mode of administration of each hormone is different. For example, IGF-I is administered subcutaneously, testosterone is given in a gel, and pregnenolone is administered via capsule (see page 32-34 and page 23-24, table I). Since the reference discloses different modes of administration, they would have to be administered separately. The language of symptoms associated with multiple sclerosis is an intended use limitation and intended use or field of use. Such language will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*.

Therefore, the reference anticipates the claimed invention.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta
Patent Examiner